K002359

OCT 1 9 2000

SUMMARY OF 510 (k) SAFETY AND EFFECTIVENESS INFORMATION

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR 807.92.

MDI Gliadin G Test reagents (P/N: GLKi-A) are intended for the qualitative and semi-quantitative determination of IgG antibodies to gliadin in human serum. The principal diagnostic value of this test is detection of anti-gliadin IgG, which is used as an aid in patients with Celiac Disease.

The Micro Detect, Inc. Gliadin IgG assay reagents (**MDI Gliadin IgG Test**) is intended to be used as a manual procedure. The reagents are supplied as a micro plate coated with specific antigen, Controls, Wash Buffer, Sample Diluent, Conjugate, Substrate, and Stop Solution.

The performance of MDI Gliadin G Test was determined using patient specimens. The assay results were compared with the results obtained using predicate assay. A correlation study was conducted on 199 patient specimens from both genders (51% male and 49% female), different races and various ages (26% from 1-17 years and 74% from 17-78 years old subjects). Of the 199 specimens tested 95 were negative and 104 were positive for the presence of IgG antibodies to Gliadin. The performance of MDI Gliadin IgG Test is shown in the following table:

Predicate		**MDI Gliadin G Test**			Total
		+	-	+/-	
Pos.	104	103 (A)	0 (B)	1	104
Neg.	95	1 (D)	94 (C)	0	95
+/- *	0	0	0	0	0
Total	199	104	94	1	199

* Pos/Neg. specimens were omitted for the calculations of performance

In addition, one hundred twenty random serum samples obtained from a clinical lab

were also tested on MDI Gliadin IgG Test for the presence of IgG antibodies to Gliadin. Random specimens were also from both genders, different races and various ages(few months to 99 years old).

The patient results obtained using the **MDI Gliadin G Test** is substantially equivalent to those obtained by using predicate assays:

Relative Sensitivity:	100%
Relative Specificity:	99%
Overall Agreement:	99.5%

Precision (%CV): 1.68 –5.6(Inter) and 1.4 – 6.9(Intra)

Stability: One year at 2-8°C. The stability of the **MDI Gliadin G Test** Kit for the detection of IgG antibodies to gliadin was found to be one year at 2-8°C. This was predicted from studies done under stress condition (37°C).

No cross reactivity with *H. pylori,* ds-DNA, Rheumatoid Factor and various ENAs was detected on MDI Gliadin IgG Test.

The Micro plate ELISA formats is a commonly used format for the detection of many entities of clinical interest, including Celiac Disease.

The **MDI Gliadin G Test** system is shown to provide results, which are substantially equivalent to those, obtained by a predicate product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 1 9 2000

Mehdi Alem, Ph.D.
President
Micro Detect, Inc.
2852 Walnut Avenue, Suite H-1
Tustin, California 92780

Re: K002359
Trade Name: MDI Gliadin G Test
Regulatory Class: II
Product Code: MST
Dated: September 28, 2000
Received: September 29, 2000

Dear Dr. Alem:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K002359/A1

510(k) Number (if known): K002359

Device Name: MDI Gliadin GTest

SK-20

Indications For Use:

The **MDI Gliadin IgG Test** is a semi- quantitative enzyme immunoassay (EIA) kit for the detection of IgG antibodies against gliadin in human serum. The test is intended as an aid in the diagnosis of Celiac Disease. FOR *IN VITRO* DIAGNOSTIC USE ONLY

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter G Mahler

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002359

Prescription Use ✓
(Per 21 CFR 801,109)

OR

Over-The-Counter Use___

(Optional Format 1-2 -96)